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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/717,665 11/21/2003		Zairen Sun	ORIGEN-0009-D01	9053	
23599	7590 04/13/2006		EXAMINER		
,	WHITE, ZELANO & B ENDON BLVD.	HADDAD,	HADDAD, MAHER M		
SUITE 1400		ART UNIT	PAPER NUMBER		
ARLINGTO	N, VA 22201	1644	1644		
			DATE MAIL ED: 04/13/2004	4	

Please find below and/or attached an Office communication concerning this application or proceeding.

		Applicat	ion No	Applicant(s)				
Office Action Summary		10/717,6		SUN ET AL.				
		Examine		Art Unit				
			. Haddad	1644				
	The MAILING DATE of this communicat			<u> </u>	ddress			
Period fo					-0.5.00			
WHIC - Exter after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR CHEVER IS LONGER, FROM THE MAIL nsions of time may be available under the provisions of 37 SIX (6) MONTHS from the mailing date of this communic period for reply is specified above, the maximum statutor to reply within the set or extended period for reply will, reply received by the Office later than three months after the patent term adjustment. See 37 CFR 1.704(b).	LING DATE OF T 7 CFR 1.136(a). In no e tation. ary period will apply and by statute, cause the ap	HIS COMMUNICATION IN THE PROPERTY OF THE PROPE	N. imely filed on the mailing date of this of ED (35 U.S.C. § 133).				
Status					•			
1)⊠	Responsive to communication(s) filed o	on 09 February 2	006					
2a)□	This action is FINAL . 2b)⊠ This action is non-final.							
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,	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.							
Dispositi	ion of Claims							
4)⊠	4)⊠ Claim(s) <u>1-34</u> is/are pending in the application.							
• —	4a) Of the above claim(s) <u>1-6 and 11-31</u> is/are withdrawn from consideration.							
5)[5) Claim(s) is/are allowed.							
6)⊠)⊠ Claim(s) <u>7-10 and 32-34</u> is/are rejected.							
7)								
8)[Claim(s) are subject to restriction	n and/or election	requirement.					
Applicati	on Papers							
9)	The specification is objected to by the Ex	xaminer.						
10)	The drawing(s) filed on is/are: a)	accepted or t	o) objected to by the	Examiner.				
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).								
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.								
Priority ι	ınder 35 U.S.C. § 119							
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.								
2) 🔲 Notic 3) 🔯 Inforr	t(s) e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-9 nation Disclosure Statement(s) (PTO-1449 or PTC r No(s)/Mail Date <u>11/23/03&2/9/06</u> .		4) Interview Summar Paper No(s)/Mail D 5) Notice of Informal 6) Other: <u>Attached se</u>	Date Patent Application (PT)	O-152)			

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DETAILED ACTION

- 1. Claims 1-34 are pending.
- 2. Applicant's election of Group 51, claims 7-10 (now claims 7-10 and 32-34) directed to an isolated differentially-regulated human angiogenesis polypeptide of SEQ ID NO: 44 filed on 2/9/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
- 3. Claims 1-6 and 11-31 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.
- 4. Claims 7-10 and 32-34 are under examination as they read on an isolated differentially-regulated human angiogenesis polypeptide of SEQ ID NO: 44.
- 5. The specification on page 1 should be amended to reflect the status of 10/164,595 and the relationship between 10/164,595 and the instant application.
- 6. Applicant's IDS, filed 2/9/06 and 11/21/03, is acknowledged, however, reference 8 was crossed out because it is duplicate of reference 6.
- 7. The specification is objected to under 37 CFR 1.821(d) for failing to provide a sequence identifier for each individual sequence. Figures 1-19, on page 1 have described several amino acid sequences that each must have a sequence identifier. Correction is required.
- 8. Claims 7-10 are objected to because they depend on non elected claims 1-4, respectively.
- 9. Claim 32 is objected to for the following informalities: the "a by" recited in claim 32, lines 4 is improper. Deletion is required.
- 10. The following is a quotation of the second paragraph of 35 U.S.C. 112.

 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 11. Claims 7-10 and 32-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
 - A. Claims 7-10 are indefinite because they recite polypeptides but depend from a polynucleotide claims 1-4, respectively.
 - B. The recitation "which is coded for a by a polypeptide which hybridizes" in claim 32 is indefinite and ambiguous because 1) it is unclear how a polypeptide would be coded for

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another polypeptide and 2) it is unclear how a polypeptide would hybridize to a polynucleotide.

C. The "polypeptide fragment" recited in claims 33-34 has no antecedent basis in base claim 32. Base claim 32 only recites an isolated polypeptide.

12. 35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

13. Claims 7-10 and 32-34 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility.

Applicant is directed to the Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday January 5, 2001.

The instant application has provided a description of isolated polypeptides of SEQ ID NO: 44 encoded by SEQ ID NO: 43 and an antibody to said polypeptides. The instant application does not disclose the biological role of the protein or its significance. The specification also asserts that the claimed ANH0757 polypeptide, which is encoded by differentially regulated gene in angiogenesis comprises a bZIP transcription factor domain at amino acids 519-583 of SEQ ID NO: 44 (see page 59, row 5). The specification further asserts that the gene expression profile of the encoded polypeptide of SEQ ID NO: 44 is U1S H (see table 3, page 63, row 23) indicating that the gene up-regulated at 1-hour, and remained (sustained) up in the 8- and 24-hour assays high (H). Further the specification asserts that polynucleotide of ANH0757 have been mapped to 5q35.2 chromosomal band which associated with congenital development disorder (see page 61, row 1). Furthermore, the specification asserts that the claimed polypeptides of SEQ ID NO: 44 can be utilized in therapeutic applications, especially to treat diseases and conditions of vascular tissue, including angiogenesis, such as immunotherapy, vaccination, protein or polypeptide replacement therapy, among other (see page 45 lines 15-21).

However, neither the instant specification or the art of record identifies even a single disease or disorder which has been shown to be associated with the claimed SEQ ID NO: 44 of the instant invention has not been shown to be differentially expressed in any disease or disorder, the claimed polypeptide cannot be employed in a diagnostic capacity. The specification does not teach how to extrapolate data obtained from the gene expression profile studies to the development of a therapeutic treatment. The increased copy number of DNA does not provide a readily apparent use for the polypeptide, for which there is no information regarding level of expression, activity, or role in angiogenesis. For example, Pennica et al (PNAS 95:14717-14722, 1998) provides an example where the DNA copy number is amplified but the RNA expression is actually reduced.

There must be some expression pattern that would allow the claimed polypeptide of SEQ ID NO: 44 to be used in a diagnostic manner. Many proteins are expressed in normal tissue and diseased

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tissues. Therefore, one needs to know, e.g., that the polypeptide is either present only in a angiogenic tissue, to the exclusion of normal or is expressed in higher level in diseased tissue compared to normal tissue (i.e. overexpression). However, in the absence of any disclosed relationship between the claimed polypeptide and any disease or disorder and the lack of any correlation between the claimed polypeptide with any known disease or disorder, any information obtained from any expression profile would only serve as the basis for further research on the observation itself. "Congress intended that no patent be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing" Brenner, 148 USPQ at 696. The disclosure does not present a substantial utility that would support the requirement of 35 U.S.C. §101.

- 14. The following is a quotation of the first paragraph of 35 U.S.C. 112:
 - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 15. Claims 7-10 and 32-34 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

Further, besides the isolated polypeptide of SEQ ID NO: 44, the specification fails to provide any guidance as to how to *make* an isolated differentially-regulated human angiogenesis polypeptide having the sequences set forth in SEQ ID NO: 44 as claimed in claims 7-10, or an isolated polypeptide which is a polypeptide "having at least 90% identity along its entire length" to the complete amino acid sequence set forth in SEQ ID NO: 44 and which is coded for a polypeptide which hybridizes under high stringency conditions to the complete complement of the polynucleotide sequence set forth in SEQ ID NO: 43 in claim 32 or an isolated polypeptide fragment of claim 32 as claimed in claim 33, or an isolated polypeptide fragment of claim 32, which comprises amino acids 1-448, 448-449, or 532-639 of SEQ ID NO: 44. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with this claim.

The specification discloses amino acid sequences of SEQ ID NO: 44 encoded by SEQ ID NO: 43. The instant claims encompass in their breadth any polypeptide having 90% or more amino acid sequence identity along its entire length to the polypeptide sequence of SEQ ID NO: 44 or any isolated polypeptide fragment of SEQ ID NO: 44 or an isolated polypeptide fragment which comprises amino acids 1-44, 448-449 or 532-639 of SEQ ID NO: 44.

The terms "having" "comprises" are open-ended (See MPEP 2111.03) and extend the variant polypeptides to include additional unspecified amino acids on either or both termini. There does not appear to be sufficient guidance in the specification as filed as to how the skilled artisan would make the various amino acids recited in the instant claims. A person of skill in the art

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would not know which sequences are essential, which sequences are non-essential, and what particular sequence lengths identify essential sequences. There is insufficient guidance to direct a person of skill in the art to select particular sequences or sequence lengths as essential. Without detailed direction as to which amino acid sequences are essential to the function of the polypeptide, a person of skill in the art would not be able to determine without undue experimentation which of the plethora of amino acid sequences encompassed by the instant claims would share the function of the polypeptide of SEQ ID NO: 44, other than the amino acid of SEQ ID NO:44.

Further, there is tremendous variability in the importance of individual amino acids in protein sequences. Since the bZIP transcription factor domain is a key determinants of activity of claimed SEQ ID NO: 44, residue substitutions that are conservative (e.g., Glu in equilibrium Asp, Asn in equilibrium Asp, Ile in equilibrium Leu, Lys in equilibrium Arg and Ala in equilibrium Gly) can have severe phenotypic effects. There is no simple way to infer the likely effect of an amino acid substitution on the basis of sequence information alone. Therefore, one skill in the art would not be able to predicted what residue substitutions can replace the amino acid residues in the disintegrin domain without affecting it function.

The art acknowledges that function cannot be predicted based solely on structural similarity to a protein found in the sequence databases and recognized that it was unpredictable if any functional activity will be shared by two polypeptides having less than 100% identity over the full length of their sequences. Attwood (Science 2000; 290:471-473) teaches that "[i]t is presumptuous to make functional assignments merely on the basis of some degree of similarity between sequences.

The instant claim language appears to encompass subsequences. For example, claims 32-33 recites a polypeptide fragment having at least 90% identity along its entire length to the complete amino acid sequence of SEQ ID NO: 44. However, the specification does not appear to have provided sufficient guidance as to which subsequences of SEQ ID NO:44 would share the function of SEQ ID NO:44. Neither does the specification appear to have provided any working examples of any functional subsequences. Thus it would require undue experimentation of the skilled artisan to determine which subsequences of SEQ ID NO:44 would have the function of the full length molecule, and in turn identify nucleic acid subsequences of SEQ ID NO:43 which encode these subsequences

Therefore, the specification fails to provide sufficient guidance as to which changes in the core structure of SEQ ID NO: 44 is essential for maintain its biological activity and which changes can be made in the structure of SEQ ID NO: 44 and still maintained the same function. The specification fails to provide guidance to the role of bZIP transcription factor domain sequence within the disintegrin domain of SEQ ID NO: 44 in function of the claimed polypeptide. The specification does not provide sufficient guidance as to what amino acids within the angiogenesis polypeptide can be change without affecting the function.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary the limited working examples, the

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nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

16. Claims 7-10 and 32-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of the isolated polypeptide of SEQ ID NO: 44 encoded by SEQ ID NO: 43.

Applicant is not in possession of any isolated differentially-regulated human angiogenesis polypeptide having the sequences set forth in SEQ ID NO: 44 as claimed in claims 7-10, or an isolated polypeptide which is a polypeptide "having at least 90% identity along its entire length" to the complete amino acid sequence set forth in SEQ ID NO: 44 and which is coded for a polypeptide which hybridizes under high stringency conditions to the complete complement of the polynucleotide sequence set forth in SEQ ID NO: 43 in claim 32 or an isolated polypeptide fragment of claim 32 as claimed in claim 33, or an isolated polypeptide fragment of claim 32, which comprises amino acids 1-448, 448-449, or 532-639 of SEQ ID NO: 44.

Applicant has disclosed the amino acid of SEQ ID NO: 44 encoded by SEQ ID NO: 43; therefore, the skilled artisan cannot envision all the contemplated amino acid sequence possibilities recited in the instant claims. Consequently, conception cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC1993). The Guidelines for the Examination of Patent Application Under the 35 U.S.C.112, ¶ 1"Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 20001, see especially page 1106 3rd column).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the final Guidelines for the Examination of Patent Applications Under

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the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 18. Claims 9-10 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Carninci et al (Genome Res. 10:1617-1630, 2000).

Carninci et al teaches a 640 amino acids polypeptide having 93.7% identity along its entire length to the complete amino acid sequence of claimed SEQ ID NO: 44 (see attached sequence alignment in particular). The referenced polypeptide would be encoded by a polynucleotide which hybridizes under high stringency conditions to the complete complement of polynucleotide sequence of SEQ ID NO: 43.

The reference teachings anticipate the claimed invention.

- 19. No claim is allowed.
- 20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

April 3, 2006

Maher Haddad, Ph.D. Patent Examiner

Maker Haddad

Technology Center 1600

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RC STRAIN-657BL/GJ; TISSUB=Testis;

RA Adachi J., Aizawa K., Akimura T., Hara A., Hashizume W.,

Pukuda S., Furuno M., Hanagaki T., Hara A., Hashizume W.,

RA Hayashida K., Hayatsu N., Hiramoto K., Hiraoka T., Hirozane T.,

RA Hori F., Imotani K., Ishii Y., Itoh M., Kagawa I., Kasukawa T.,

RA Katoh H., Kawai J., Kojima Y., Kondo S., Konno H., Kouda M., Koya S.,

RA Kurihara C., Matsuyama T., Miyazaki A., Murata M., Nakamura M.,

RA Nishi K., Nomura K., Numazaki R., Ohno M., Ohasto N., Okazaki Y.,

RA Salto R., Saitoh H., Sakai C., Sakai K., Sakazume N., Sano H.,

RA Sasaki D., Shibata K., Shinagawa A., Shiraki T., Sogabe Y., Tagami M.

Tagawa A., Takahashi F., Takaku-Akahira S., Takeda Y., Tanaka T.,

Tomaru A., Toya T., Yasunishi A., Muramatsu M., Hayashizaki Y.;

LI Submitted (JUL-2001) to the EMBL/GenBank/DDBJ databases.

RMBL; AK030092; BAC26779.1; ", mRNA.

RMGI:1924378; A930001N09Rik.

NR InterPro; IPR004827; TP bZIP.

NR HYDOFNEYS PS00036; BZIP_BASIC; UNKNOWN_1. Query Match Best Local S Matches 598 NUCLEOTIDE SEQUENCE.

STRAIN-C57BL/6J; TISSUE-Testis;

MEDLINE-20499374; PubMed=11042159; DOI=10.1101/gr.145100.

MEDLINE-20499374; PubMed=11042159; DOI=10.1101/gr.145100.

Carninci P., Shibata Y., Hayatsu N., Sugahara Y., Shibata K., It.

Konno H., Okazaki Y., Muramatsu M., Hayashizaki Y.;

"Normalization and subtraction of cap-trapper-selected cDNAs to prepare full-length cDNA libraries for rapid discovery of new ge Genome Res. 10:1617-1630(2000). Kuehl P., Lewis S., Matsuo Y., Nikaido I., Pesole G., Quackenbush J., Schriml L.M., Staubli F., Suzuki R., Tomita M., Wagner L., Washio T., Sakai K., Okido T., Puruno M., Aono H., Baldarelli R., Barsh G., Blake J., Boffelli D., Bojunga N., Carminci P., de Bonaldo M.F., Brownstein M.J., Bult C., Fletcher C., Fujita M., Gariboldi M., Gustincich S., Hill D., Hofmann M., Hume D.A., Kamiya M., Lee N.H., Lyons P., Marchionni L., Mashima J., Mazzarelli J., Mombaerts P., Nordone P., Ring B., Ringwald M., Rodriguez I., Sakamoto N., Sasaki H., Sato K., Schoenbach C., Seya T., Shibata Y., Storch K.-F., Suzuki H., Toyo-oka K., Wang K.H., Weitz C., Whittaker C., Wilming L., Wynshaw-Boris A., Yoshida K., Hasegawa Y., Kawaji H., Kohtsuki S., Hasegawa Y., Kawaji H., Kohtsuki S., NUCLEOTIDE SEQUENCE.
STRAIN=C57BL/6J; TISSUE=Testis;
The PANTOM Consortium, the RIKEN Genome Exploration Research "Analysis of the mouse transcriptome 60,770 full-length cDNAs.";
Nature 420:563-573(2002). Nature 409:685-690(2001). Kadota K., Matsuda H.A., Pleischmann W., Gaasterle "Functional annotation of a full-length mouse cDNA collection."; Hayashizaki Y.; NUCLEOTIDE SEQUENCE uda H.A., Ashburner M., Batalov S., Casavant T., Gaasterland T., Gissi C., King B., Kochiwa H., S., Matsuo Y., Nikaido I., Pesole G., Quackenbush 93.7%; 72598 MW; Regearch Group Phase I & II Team; criptome based on functional annotation of Pred. Score 3136.5; FE02C532FA34E1DE No. 1.4e-139; DB 2; CRC64; Length Tanaka T., 640; . Itoh genes."; . .

Similarity

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Mismatches

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Koehrer K., Beyer A., Mewes H.W., Weil B., Ami
Robo G., Han M., Wiemann S.;
Robo G., Han M., Wiemann S.;
Submitted (JAN-2005) to the EMBL/GenBank/DDBJ
EMBL; BX647573; CAI46104.1; -; mRNA.
InterPro; IPR004827; TF bZIP.
PROSITE; PS00036; BZIP_BASIC; UNKNOWN_1.
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Hypothetical protein DXFZp313F2319 (Fragment).
Name=DXFZp313F2319;
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Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
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